UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. CONFIRMATION NO. | | |
|--|------------------------------------|------------------------|--------------------------------------|---------------|--|
| 10/753,669 | 01/08/2004 | Donald C. Roe | 7537CQ | 7CQ 1141 | |
| | 7590 01/22/200 R & GAMBLE COMP. | EXAMINER | | | |
| Global Legal Do | | STEPHENS, JACQUELINE F | | | |
| Sycamore Building - 4th Floor 299 East Sixth Street | | | ART UNIT | PAPER NUMBER | |
| CINCINNATI, | ОН 45202 | 3761 | | | |
| | | | | | |
| | | | MAIL DATE | DELIVERY MODE | |
| | | 01/22/2009 | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | Applicat | ion No. | Applicant(s) | | |
|---|--|---|--|--|-----------|--|
| Office Action Summary | | 10/753,6 | 69 | ROE ET AL. | | |
| | | Examine | r | Art Unit | | |
| | | Jacquelir | e F. Stephens | 3761 | | |
| Period for | The MAILING DATE of this communic | cation appears on th | e cover sheet with the d | correspondence add | dress | |
| A SHO WHICH - Extens after SI - If NO p - Failure Any rep | RTENED STATUTORY PERIOD FOR MEVER IS LONGER, FROM THE MARIONS of time may be available under the provisions of X (6) MONTHS from the mailing date of this community of the reply within the set or extended period for reply by the office later than three months af patent term adjustment. See 37 CFR 1.704(b). | AILING DATE OF T of 37 CFR 1.136(a). In no e unication. tutory period will apply and v vill, by statute, cause the ap | HIS COMMUNICATION vent, however, may a reply be tin vill expire SIX (6) MONTHS from plication to become ABANDONE | N. nely filed the mailing date of this co D (35 U.S.C. § 133). | | |
| Status | | | | | | |
| 2a)⊠ 1 3)□ S | Responsive to communication(s) filed his action is FINAL . Since this application is in condition followed in accordance with the practic | b)⊠ This action is or allowance excep | t for formal matters, pro | | merits is | |
| Dispositio | n of Claims | | | | | |
| 5)□ (6)⊠ (7)□ (8)□ (Applicatio | • | e withdrawn from co | onsideration. | | | |
| 10)□ T A | he specification is objected to by the he drawing(s) filed on is/are: Applicant may not request that any objected to the path or declaration is objected to | a) accepted or b tion to the drawing(s) the correction is requi | be held in abeyance. See red if the drawing(s) is ob | e 37 CFR 1.85(a). jected to. See 37 CF | ` ' | |
| Priority ur | der 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s | | | A) Diptomion O | (DTO 442) | | |
| 2) Notice 3) Informa | of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PT ation Disclosure Statement(s) (PTO-1449 or F No(s)/Mail Date | | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal F 6) Other: | | -152) | |

Application/Control Number: 10/753,669 Page 2

Art Unit: 3761

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 10/13/08 have been fully considered but are not persuasive. Applicant argues Everhart does not teach or suggest biosensor including at least one bio-recognition element adapted to interact selectively with one or more pathaogenic microorganisms. Applicant argues Everhart teaches a chemically reactive means that is unspecified except for two examples. In one example the chemically reactive means is described as adapted to give a visual indication of glucose concentration in urine. In the other example, another chemically reactive means is descibed as adapted to detect nitrite in urine. Applicant has defined a biosensor in the specification as being able to detect one or more target pathogenic microorganisms such as an envzme sensor, organella sensor, tissue sensor, microoganism sensor, immunosensor, or electrochemical sensor. Everhart teaches the chemically reactive means in an enzyme sensor (col. 3, lines 59-61). Additionally, Everhart teaches the chemical reactive means provides a visual signal of detection of the one or more pathogenic microorganisms (Abstract, col. 3 lines 53-57). Therefore, the rejection under Evherhart and Al-Sabah is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 4. Claims 1-11, 15-19, 21-25, 36-39, and 40-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Everhart et al. USPN 5468236.

As to claims 1-10, and 40-47 Everhart teaches a disposable absorbent article comprising a sensor for detecting analytes in bodily waste or on a user's skin. Everhart discloses a disposable article comprising a topsheet **14**, a backsheet **12**, and an absorbent core **16** as claimed ('236 Figure 2). Everhart disclose the target analyte may include a health or nutritional marker ('236 col. 3, lines 10-29), which may be an enzyme, endogenous secretion, proteinaceous matter, or microorganism (col. 3, lines 56-65). Everhart generally teaches a chemically reactive means (biosensor) that reacts with a substance present in bodily excrement. The chemical reactive means provides a visual signal of detection of the one or more pathogenic microorganisms (Abstract, col. 3 lines 53-57). Everhart teaches a chemically reactive substance acting upon

Art Unit: 3761

mammalian bodily excrement that provides the types of substance present and an estimate of the concentration of the substance (Everhart col. 3, lines 21-29).

Regarding claim 11, the invention of Everhart provides a visual indication of a substance upon reacting with body excrement. Body excrement, particularly perspiration, may not necessarily provide clinically observable symptoms, such as a skin rash. In this manner, the invention of Everhart would provide information to the wearer prior to clinically visible symptoms.

Regarding claims 15-19, the sensor provides a signal to the wearer, caregiver, or an actuator ('236 Abstract) as broadly as claimed.

Regarding claims 21 and 23, the sensor is affixed to a substrate ('236, col. 6, lines 4-6).

Regarding claims 22 and 24, the sensor is detachable from the article ('236 col. 6, lines 26-32).

Regarding claims 25 and 48, the sensor may adhere to a wearer's skin ('236, Abstract).

Regarding claims 36-39 and 49-52, Everhart describes a biosensor for detecting a target analyte upon excretion of bodily fluids or waste materials. Everhart provides a response within a period of time that stays valid until the article is discarded. The response factor would have been obvious by optimizing the type of biosensor materials

since the invention of Everhart is used in the same environment and problem that is solved is the same as the claimed invention. Moreover, discovering optimum values only involves routine skill in the art, In re Boesch, 617 F. 2d 272, 205 FUSPQ 215 (CCPA 1980).

5. Claims 28-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Everhart et al. USPN 5468236 in view of Al-Sabah USPN 5868723.

As to claims 28-31, Everhart disclose the present invention substantially as claimed. However, Everhart fail to disclose the disposable article has an actuator. Al-Sabah discloses an absorbent article comprising an actuator 43, which comprises a power source 42(Figure 7). The actuator performs a responsive function when the sensor detects an input (Abstract). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate an actuator as taught in Al-Sabah to the sensor apparatus of Everhart. Doing so would provide a means for alerting the user or a health care professional of the presence of the target analyte.

As to claims 32 and 33, Everhart/Al-Sabah teaches a receiver integral with the article (Al-Sabah col. 5, lines 35-37).

As to claim 34 and 35, Everhart/Al-Sabah teaches a transmitter (Al-Sabah col. 5, lines 1-4).

Application/Control Number: 10/753,669 Page 6

Art Unit: 3761

Conclusion

6. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline F. Stephens whose telephone number is (571) 272-4937. The examiner can normally be reached on Monday-Friday 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/753,669 Page 7

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jacqueline F Stephens/ Primary Examiner, Art Unit 3761